



ROTHWELL, FIGG, ERNST & MANBECK, P.C.

607 14th Street, N.W.  
Suite 800  
Washington, D.C. 20005

Telephone (202) 783-6040  
Facsimile (202) 783-6031  
www.rfem.com  
info@rfem.com

G. Franklin Rothwell  
(1928-2011)

E. Anthony Figg  
Harry F. Manbeck, Jr.  
George R. Repper  
Steven Lieberman  
Joseph A. Hynds  
Martin M. Zoltick  
R. Danny Huntington  
Joo Mee Kim  
Richard Wydeven  
Sharon L. Davis  
Robert B. Murray  
Jeffrey L. Ihnen  
Brian S. Rosenbloom  
Jason M. Shapiro  
Brian A. Tollefson  
C. Nichole Gifford  
R. Elizabeth Brenner-Leifer  
Nancy J. Linck, Ph.D.  
Sharon E. Crane, Ph.D.  
Lisa N. Phillips  
Steven P. Weihrouch  
Robert P. Parker  
Jenny L. Colgate

\*Not a member of the D.C.  
Bar. Practice limited to patent,  
trademark and copyright matters  
and cases in federal courts.

Leo M. Loughlin  
Monica Chin Kitts  
Michael V. Battaglia  
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Jennifer P. Nock  
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Chen Li  
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Soumya P. Panda\*  
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Joanna M. Grigas  
Daniel R. McCallum  
Abdul Q. Basit  
Thomas C. Chen  
Peter J. Park\*  
Longhao Wang\*  
Mark T. Rawls\*  
Sarah M. Cork, Ph.D.\*  
Nechama E. Potasnick\*  
Dennis Ostrovsky, Ph.D.\*

Of Counsel  
William N. Hugnet  
Mary Frances Love

February 13, 2015

Honorable Alison J. Nathan  
United States District Judge  
Thurgood Marshall United States Courthouse  
40 Foley Square, Room 906  
New York, New York 10007

Re: *Braintree Laboratories, Inc. v. Breckenridge Pharmaceutical, Inc.*  
Case No.: 12-cv-6851-AJN

Dear Judge Nathan:

We represent Defendant Breckenridge Pharmaceutical, Inc. ("Breckenridge") in the above-referenced action. Pursuant to this Court's August 13, 2014 order (D.I. 71), we submit this letter on behalf of Breckenridge regarding the status of this case and of the proceedings in *Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*, No. 3:11-cv-01341 (D.N.J.) ("the *Novel* case"). Breckenridge also responds to the letter of Plaintiff Braintree Laboratories, Inc. ("Braintree") submitted today. At this time, Breckenridge respectfully requests that the Court consider on the merits Breckenridge's Motion for Summary Judgment of Noninfringement (the "Breckenridge Motion"). (See D.I. 42-46.)

As the Court will recall, this case involves Braintree's claim that Breckenridge's Abbreviated New Drug Application ("ANDA") to market a generic equivalent of Braintree's SUPREP® product would infringe certain claims of U.S. Patent No. 6,946,149 ("the '149 patent"). The *Novel* case involves Braintree's claim that Novel's proposed generic equivalent of the SUPREP® product would infringe the '149 patent.

### **Current Status of the *Novel* Proceedings on Remand**

The *Novel* case currently is on remand following the April 22, 2014 decision of the United States Court of Appeals for the Federal Circuit. See *Braintree Labs., Inc. v. Novel Labs., Inc.*, 749 F.3d 1349 (Fed. Cir. 2014). The remand proceedings in the *Novel* case will address the issue of whether the proposed generic product meets the limitation of the '149 patent claims requiring that the composition "does not produce any clinically significant electrolyte shifts."

ROTHWELL, FIGG, ERNST &amp; MANBECK, P.C.

Honorable Alison J. Nathan

February 13, 2015

Page 2

An evidentiary hearing on that issue was originally scheduled for January 18, 2015 but was delayed to February 9-11, 2015. (Ex. A (docket in *Novel* case).) Although Braintree's letter suggests that a speedy ruling is expected, the fact is that the parties do not know when the District Court for the District of New Jersey will enter a decision in the *Novel* case. As this Court is well aware, most district courts have overwhelmingly busy dockets, and there is no guarantee that Judge Sheridan will issue a ruling in the next month or even this year.

### **Removal of the Administrative Hold in this Case is Appropriate**

Braintree and Breckenridge previously agreed that this case should remain on administrative hold pending proceedings on remand in the *Novel* case, but each party reserved the right to seek removal of the administrative hold prior to completion of those proceedings. (D.I. 68 (Joint Letter to J. Nathan dated April 29, 2014) at 2.) Much has changed since that time: this case has been stayed for over a year (since January 17, 2014) and the *Novel* case has not been resolved. (D.I. 65.) Breckenridge now requests removal of the administrative hold in this case so that this Court may consider its motion for summary judgment on the merits.

Braintree argues that this court should delay ruling until the outcome of the *Novel* case is known. However, if the District Court for the District of New Jersey finds that *Novel* infringes the '149 patent (as Braintree argues), then the *Novel* case has no bearing on this case. As discussed below, Breckenridge's noninfringement argument is entirely independent of the arguments in the *Novel* case. (D.I. 41 ¶¶ 3, 8.) The *Novel* case disposes of this case only if *Novel* is found not to infringe. Then, Breckenridge would be entitled to rely on the finding of noninfringement.<sup>1</sup> (D.I. 41 ¶ 3.) If the District Court for the District of New Jersey finds no infringement by *Novel*, however, Breckenridge expects that Braintree would appeal that ruling. A second Federal Circuit appeal of the *Novel* case would take approximately a year to resolve, during which time we presume Braintree would argue that Breckenridge should be barred from marketing its product.

There is a strong public interest in providing low-cost generic drugs to consumers with minimum delays. *See, e.g., Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1344 (Fed. Cir. 2007) (noting a goal of the Hatch-Waxman Act is "to enable competitors to bring cheaper, generic . . . drugs to market as quickly as possible"). Breckenridge respectfully requests that this Court remove the administrative hold in this case and adjudicate Breckenridge's Motion on the merits.

### **The Breckenridge Motion is Entirely Independent of the Novel Case**

The parties in this case completed briefing on the Breckenridge Motion on August 13, 2013. (D.I. 55, 56.) The Breckenridge Motion argues that, as a matter of law, Breckenridge's

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<sup>1</sup> Braintree's letter states that Breckenridge's Motion based on the "from about 100 ml to about 500 mL" claim limitation is "the sole noninfringement defense that Breckenridge may assert in this litigation." This is incorrect. The parties have stipulated that Breckenridge also may rely on any final judgment of noninfringement in the *Novel* case. (D.I. 41 ¶ 3.)



ROTHWELL, FIGG, ERNST &amp; MANBECK, P.C.

Honorable Alison J. Nathan

February 13, 2015

Page 3

ANDA product cannot infringe the '149 patent because Breckenridge's ANDA requires that its product be administered in a total volume of 946 ml, while every claim of the '149 patent requires a volume of "about 100 ml to about 500 ml." (D.I. 43.) Breckenridge reserved the right to pursue this noninfringement argument regardless of the outcome of the proceedings in the *Novel* case because it is separate and distinct from the issues raised by Novel. ((D.I 41 ¶¶ 3, 8.)

Breckenridge's noninfringement argument involving the volume limitation was not made in Novel's appeal to the Federal Circuit. To the extent this argument was made at all in the *Novel* case, it only was raised obliquely during district court proceedings. As Braintree has admitted, "Novel did not appeal the district court's rejection of that noninfringement argument (and instead appealed the district court's infringement finding on other grounds), but Judge Dyk raised this issue on appeal *sua sponte*." (D.I. 68 at 2.)

Despite the fact that Novel never raised the issue, Judge Dyk authored a dissenting opinion cogently explaining that a finding of noninfringement was warranted on the basis of the volume limitation. *Braintree v. Novel*, 749 F.3d at 1360-65. There is no basis to conclude that the other two panel members disagreed with Judge Dyk's analysis. It is likely that the other panel members simply did not consider the issue because it was not raised on appeal. Federal Circuit precedent is clear that arguments not fully presented in a party's opening briefs are waived. *See Whitserve, LLC v. Computer Packages, Inc.*, 694 F.3d 10, 20 nn. 4 and 5 (Fed. Cir. 2012) (finding waiver of district court error alluded to in opening appeal brief, but not set forth in the statement of issues and unsupported by any legal citations); *see also SmithKline Beecham v. Apotex Corp.*, 439 F.3d 1312, 1320 (Fed. Cir. 2006) ("[A]rguments raised in footnotes are not preserved."). Here, it is undisputed that Novel did not argue noninfringement based on the volume limitation in its appeal at all. (*See* D.I. 68 at 2.) Similarly, it is no more possible to divine the significance of the Federal Circuit's denial of rehearing *en banc* than it is to determine the reason the Supreme Court denies *certiorari* in a given case. *En banc* review is reserved for "question[s] of exceptional importance," not arguments the parties failed to raise on appeal. *See* F.R.A.P. 35(a).

Breckenridge believes that no further briefing is required on the Breckenridge Motion and that this issue is ripe for the Court's review. If the Court would find it helpful, however, Breckenridge proposes that the parties submit short supplemental briefs addressing the issue of whether the Federal Circuit ruling in *Braintree v. Novel* affects Breckenridge's noninfringement arguments based on the volume limitation of the '149 patent claims. Breckenridge believes that such briefing would require no more than three pages per side and could be submitted simultaneously by February 27, 2015.

Respectfully submitted,


  
Steven Lieberman

cc: All counsel of record

**CERTIFICATE OF SERVICE**

I hereby certify that on February 13, 2015, a true and correct copy of the foregoing **LETTER FROM STEVEN LIEBERMAN TO JUDGE NATHAN** was filed through the Court's Electronic Filing System (ECF), and was served electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Erik van Leeuwen  
Erik van Leeuwen  
Litigation Operations Manager  
Rothwell, Figg, Ernst & Manbeck, P.C.